510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K062575

1. Date of Summary: August 28, 2006

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   Tel:732-274-1000
   Fax:732-274-1010

NOV 2 6 2007

3. Device Name:
   Trade Names: AccuSign® RC·DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   StatusFirst® DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   Common or Usual Name: Immunoassay for detection of abused drugs in human urine
   Classification Name: Drugs of abuse test systems, Clinical toxicology test system

4. Identification of legally marketed device to which claims equivalence:
   k983501: AccuSign® DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)
   by Princeton BioMeditech Corporation

5. Device Description:
   The AccuSign® RC·DOA 10 test device is a simple immuno-chromatographic test for the rapid, qualitative detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, amphetamine and/or their metabolites in human urine. The test result can be read visually or with DXpress reader (k050955).

6. Intended Use:
   AccuSign® RC·DOA 10 is intended to use for the qualitative detection of methamphetamine, opiates, cocaine, THC, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, amphetamine, and/or their metabolites in human urine to assist in screening of drugs of abuse samples. For *in vitro* diagnostic use. The detecting cut-off concentrations are as follows:

MET	D-Methamphetamine	1000 ng/mL
OPI	Morphine	300 ng/mL
COC	Benzoylecgonine	300 ng/mL
THC	11-nor-Δ^9-9-carboxylic acid	50 ng/mL
PCP	Phencyclidine	25 ng/mL
Benzodiazepine	Oxazepam	300 ng/mL
Barbiturate	Secobarbital	300 ng/mL
Methadone	Methadone	300 ng/mL
TCA	Nortriptyline	1000 ng/mL
AMP	D-Amphetamine	1000 ng/mL

This test provides only a preliminary analytical result and a more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method.

7. Substantial Equivalence:
   AccuSign® RC·DOA 10 is substantially equivalent in intended use, principle and performance to the current k983501, AccuSign® DOA 10. Both assays are in vitro immunochromatographic assays with an intended use for the qualitative detection of drugs of abuse in human urine to assist in screening of drugs of abuse samples. The two products are identical and use the same formula and manufacturing processes with the same reagents. The only difference is AccuSign® RC·DOA 10, Reader reading compatible, allows an optical result reading method to customers by using a reader, DXpress, for result reading; on the other hand, AccuSign® DOA 10 is a visual read only test.

Conclusion: The device is substantially equivalent to a legally marketed device k983501.

Substantial Equivalence

AccuSign®RC·DOA 10 test is substantially equivalent to AccuSign® DOA 10, k983501 by Princeton BioMeditech Corporation.
The table below compares the AccuSign® RC·DOA 10 test to the predicate devices.

Item	AccuSign® ·DOA 10 (Predicate)	AccuSign® RC·DOA 10
Intended Use	For the qualitative detection of 10 kinds of drugs of abuse in human urine	For the qualitative detection of 10 kinds of drugs of abuse in human urine
Assay Principle	Lateral flow Immuno-chromatographic assay	Lateral flow Immuno-chromatographic assay
Test Procedure	Add 3 drops of urine into the sample well.	Add 3 drops of urine into the sample well.
Result reading time	5-10 min	5 min
Method of result reading	**Visual Read only**	**DXpress reader (k050955) or visual**
Specimen Type	Human urine	Human urine
Sample Volume	3 drops	3 drops
Detection Cutoff	D-Methamphetamine 1000 Morphine 300 Benzoylecgonine 300 11-nor-Δ^9-9-carboxylic acid 50 Phencyclidine 25 Oxazepam 300 Secobarbital 300 Methadone 300 Nortriptyline1000 D-Amphetamine 1000	D-Methamphetamine 1000 Morphine 300 Benzoylecgonine 300 11-nor-Δ^9-9-carboxylic acid 50 Phencyclidine 25 Oxazepam 300 Secobarbital 300 Methadone 300 Nortriptyline1000 D-Amphetamine 1000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 6 2007

Princeton BioMeditech Corporation
c/o Kyung-Ah Kim
4242 US Route 1
Monmouth Junction, NJ 08852-1905

Re: k062575
Trade/Device Name: AccuSign ®RC-DOA 10 (MET/OPI/COC/THE/PEP/BZO BAR/MTD/TCA/AMP
Regulation Number: 21 CFR 862.3160
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Code: LAG, DJG, DIO, DKE, DKZ, DIS, DJR, LFI, LCM, JXM
Dated: October 1, 2007
Received: October 2, 2007

Dear Dr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k062575

Device Name: AccuSign®RC·DOA10 (MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

Indications For Use:

Immunoassay for the qualitative detection of methamphetamine, opiates, cocaine metabolite, THC metabolite, phencyclidine, benzodiazepines, barbiturates, tricyclic antidepressants, methadone, and amphetamine in human urine to assist in screening of drug of abuse samples. The detecting cut-off concentrations are as follows:

MET	D-Methamphetamine	1000 ng/mL
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Methadone	Methadone	300 ng/mL
TCA	Nortriptyline	1000 ng/mL
AMP	D-Amphetamine	1000 ng/mL

This assay provides only a preliminary analytical test result. A more specific alternate chemical method m ust be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/ MS)/High performance liquid chromatography (HPLC, for TCA) are the preferred confirmatory methods. Cl inical consideration and professional judgment should be applied to any drug of abuse test result, particula rly when preliminary positive results are obtained.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k062575